

Towards new mechanisms of innovation:
How Latin America can become a R&D leader
in the field of neglected diseases



#### A market failure



Pharmaceutical companies and the offer and demand market logic



R&D focus on developed region priorities

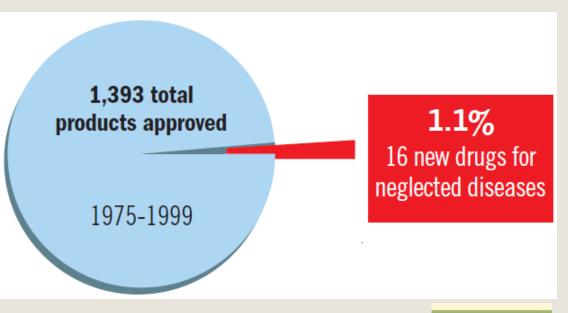


Result: the "90/10" R&D funding gap



# A Decade Ago: Research at a Standstill Fatal Imbalance for Neglected Diseases

#### Health R&D (1975 – 1999)



A Fatal Imbalance - from 1975-1999:

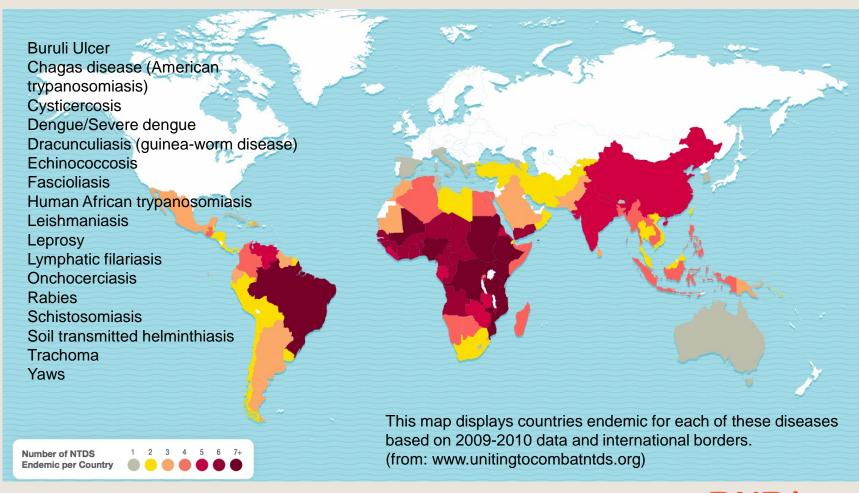
Approx. 10% of R&D dedicated to illnesses that affect 90% of global disease burden ('10/90 gap')





Source: Fatal Imbalance: The Crisis in Research and Development for Neglected Diseases, MSF, 2001

## Burden of Neglected Tropical Diseases





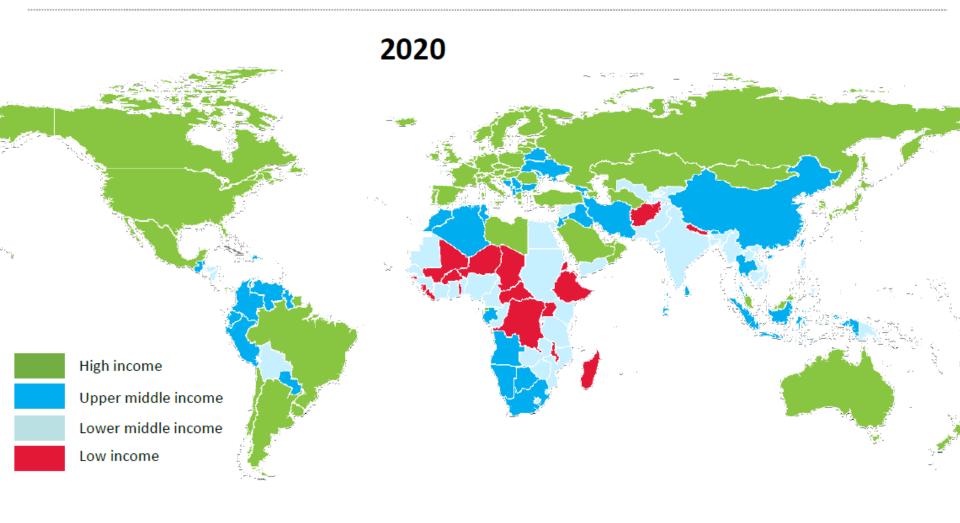
### Neglected diseases promote poverty

Nearly twice as many poor people are living in emerging economies than in low-income countries today

	Total population (in millions)	People living with less than 2\$ a day (in percentage)	People living with less than 2\$ a day (in millions)
Least Developed Countries	1000	74%	755
Emerging economies	4420	57%	1,536

Source: Michel Kazatchkine, DNDi-Institut Pasteur meeting, Dec. 2013

#### Economic growth is rapidly changing the world order



Source: IMF data, extrapolated 2017-2020

# An opportunity to seize for Latin America science



How to build a R&D model with citizens and patients at the core

Serafin Moreno
Colombian miner



### Public policies to boost innovation

R&D leadership and coordination led by LATAM

Political willingness and vision for neglected population

Open innovation to foster exchange and avoid duplication

Sustainable and adapted funding mechanisms

Favorable regulatory environments

Articulate Research capacities





## Seven cases to illustrate



# Case 1: Strengthening Research Capacities in Disease-Endemic Countries

#### **CHAGAS**



VL



HAT



#### Regional Disease Platforms:

- Defining patients' needs and target product profile (TPP)
- Strengthening local capacities
- Conducting clinical trials (Phase II/III studies)
- Facilitating registration
- Accelerating implementation of new treatments (Phase IV & pharmacovigilance studies)



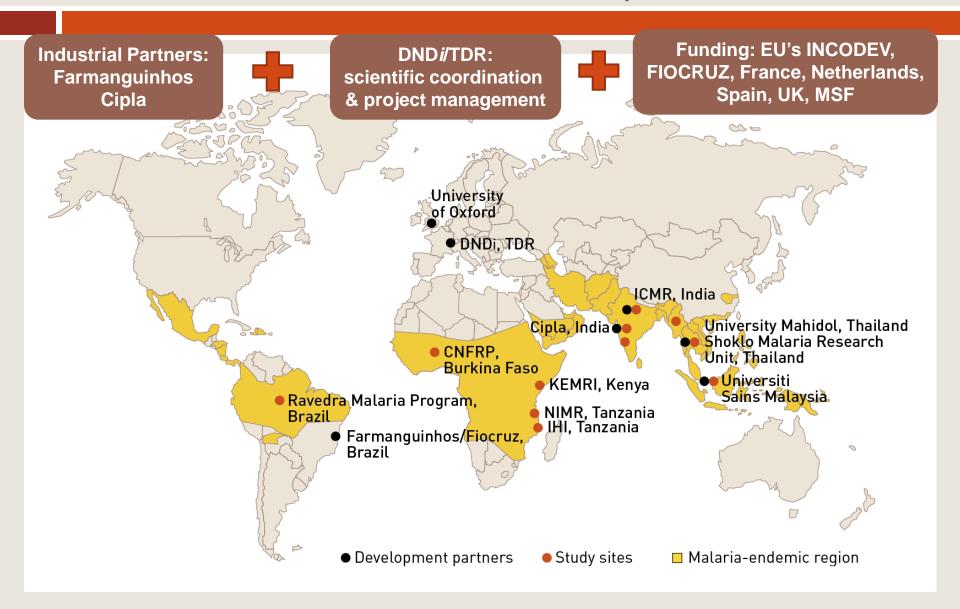
### Case 2: DNDi Partnerships in LA

#### **FOUNDING PARTNERS** UNIVERSITY-ACADEMIA Fundação Oswaldo Cruz; FRIENDS OF DNDI UNICAMP; Universidade de Sao MSF Argentina, Brasil, Paulo; Universidade de Ouro Paulo Buss: Eloan México; Institut Pasteur-Preto; Universidade de Brasilia; Pinheiro; Jose Montevideo: WHO=> UERJ; UNAM- Mexico; Temporao; PAHO Universidad Mayor San Simon -**Ricardo Preve** Bolivia; Universidade Federal do Piauí: Universidade Estadual de Montes Claros; Universidade Federal de Tocantins: Universidade Federal de Sergipe; Hospital Infantil João Paulo II, **GOVERNMENTAL** Fundação Hospitalar do Estado de **OPERATIONAL PARTNERS** Minas Gerais; Hospital São José Centro de Pesquisas René oenças Infecciosas - Forta Rachou/Fiocruz; Laboratório Farmacêutico do Estado de Pernambuco LAFEPE; Farmanguinhos REGIONAL **DND**i and Laboratório da **NETWORKS** Marinha- Brasil. **Chagas Plataform** - app 80 institutions; Red de Investigación Pediátrica-Argentina; Leish letwork Brasil PDP Medicines for **MANUFACTURERS** Malaria Venture-Geneva: **HUMAX Pharmaceutical** S.A, Medellín; Farmatech, FIND NON-GOVERNMENTAL Medellín; NORTEC **OPERATIONAL PARTNERS** Química S.A, Rio de Janeiro: NUDFAC. Núcleo CEADES- Bolivia; IS-Global-**PUBLIC DONORS** de Desenvolvimento Barcelona: BNDES; FINEP-CNPQ; Farmacêutico e Fundación Mundo Sano- Argentina; Ministério da Saúde-Cosméticos, Recife, Brasil; Carlos Slim Foundation - Mexico; Brasil; Ministerio de Cristália; Elea; Maprimed; PECET- Colombia; LAT Research, Ciencias e Tecnologia-Sanofi; GSK; Abbott Argentina; LATAM (CRO); CRO JSS Argentina; BMGF; (CRO); Federación Interacional de CONACYT

Pacientes; Federação Internacional de Pessoas Afetadas pela Doença de Chagas; The Sabin Vaccine Institute, USA; FIPEC- Argentina

Drugs for Neglected Diseases initiative

# Case 3: Artesunate-Mefloquine Fixed Dose Combination: FACT Partnership



### Case 4: Ruta N – Medellín, Colombia

Ruta N is a corporation created by the city of Medellin, academia and the industry to promote the development of innovative technology-based businesses that increase the competitiveness of the city and the region.









### Case 5: Mercosur Regulatory harmonization



- Promote and stimulate regional harmonization to aim accelerate scientific risk benefit
- Strengthen capacities of regulatory bodies in endemic countries as well as regional synergies



#### Case 6: BNDES Subcrédito Social - Brazil

#### Non-reimbursable Resources:

An existing mechanism through investments in social, educational, environmental, scientific and technological research.





# Case 7: Sustainable and transformative initiatives









## Vision for tomorrow

The Chagas R&D Accelerator Initiative: a coordination mechanism for accelerating the development of new health tools for Chagas disease—a possible regional response to World Health Assembly resolution 66.22

The Coordination Initiative: representatives of the scientific community, key Latin American governments, PAHO/WHO, TDR, DNDi, treatment providers, (FINDECHAGAS), supported by a secretariat. Agree priority project, TPP's, funding needs incentives and policies.

 Precedent within region : countries in Latin America can collaborate on funding and R&D priorities applying open innovation principles

contained in CWEG



## Chagas Accelerator

- Open knowledge and innovation policy: Institutions, companies and researchers sign a formal agreement ensuring open knowledge sharing, and data transparency and publications of results
- Funding: pull public and private funding into a virtual fund to support priority projects. Possibility of refocusing existing funding on R&D (e.g BNDES).
- Promote and support new incentive mechanims: e.g Milestone prize
- Equitable access and delinkage policy: products developed as public goods, with affordable pricing, registered in all endemic countries
- Towards a Regional TPP: building on existing platforms and promising R&D projects:
  - New PCR diagnostic kit, Laboratory validation of selected biomarkers, at least one new biomarker validated for use in clinical trials, Biobank portal, Proof of concept of alternative treatment regimens of existing drugs in monotherapy or in combination, Proof of concept of a new chemical entity (NCE), at least one new treatment option available and adopted within 5 years, and sustained diagnostic and treatment scale-up in Latin America...

#### Conclusion

A unique opportunity for the rise of Latin America, by solving old problems with innovative new solutions



